OCT 24 2000

K000418

February 4, 2000

Premarket Notification [510(k)] Summary

Submitter:

RetinaLabs.com, Inc.,
1776 Peachtree Street Suite 200 North
Atlanta, GA 30309

Phone: (404) 815-5233
Fax: (404) 873-3582

Official Correspondent: Frank J. Tighe

Trade Name: The RetinaLabs.com, Inc., PDT DoseCalculator

Common Name: Personal Computer Software

Registration Number: 1063514

Class: Class 1

Class Name: We were unable to find the device listed in the classification regulations, 21 CFR Parts 862-892 [807.87 (c)].

Panel: Ophthalmic

Product Code: N/A

Device Description: The RetinaLabs.com, Inc. PDT DoseCalculator is a simple personal computer software program that calculates the drug dose based on inputs of height, weight, mass etc. Replaces an archaic, inefficient, and error-prone manual graphical nomogram technique. Please see Device Replica Diagram in Appendix C.

Statement of indications for use. - To assist in the calculation of photodynamic therapy drug dose and treatment based on patient body surface area, weight, or mass depending on the drug manufacturer's directions for use.

Substantial Equivalence Comparison

	Body Surface Area (BSA) Calculator Hemotech Inc.	Dose Calculator Integrity Medical Software	PDT DoseCalculator RetinaLabs.com
Software Based	X	X	X
BSA Calculation	X		X
Dose Calculation		X	X

Sterility

The Device is not required to be sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frank Tighe
President
RetinaLabs.com
1776 Peachtree Street
200 North
Atlanta, Georgia 30309

OCT 2 4 2000

Re: K000418
Trade Name: PDT DoseCalculator
Regulatory Class: II
Product Code: NDC
Dated: August 8, 2000
Received: August 10, 2000

Dear Mr. Tighe:

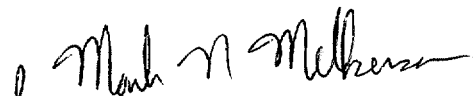
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000418

RETINALABS .com

K000418

510(k) Number: N/A

Device Name: PDT DoseCalculator (Personal Computer Software)

Indications for Use: To assist in the calculation of photodynamic therapy drug dose and treatment based on patient body surface area, weight, or mass depending on the drug manufacturer's directions for use.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X___ OR Over-The-Counter Use_____
(Per 21 CFR 8O1.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000418

OR

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